



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUL - 2 1999 6550 '99 JUL -6 P1:41

Ms. Barbara Werdelin  
33 Farmgate Road  
South Berwick, Maine 03908

Dear Ms. Werdelin:

Thank you for your letter of May 17, 1999 to Senator Susan Collins concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation. Senator Collins has asked us to respond directly to you.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of

98N 1038

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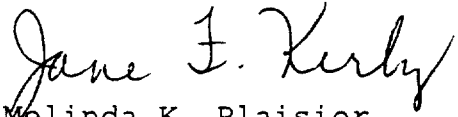
Page 2 - Ms. Barbara Werdelin

irradiated foods will take into account all of the data and information received.

Because you may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,

  
for Melinda K. Plaisier  
Interim Associate Commissioner  
for Legislative Affairs

Enclosures

cc: Dockets Management Branch  
(98N-1038)

The Honorable Susan M. Collins  
United States Senate  
Washington, D.C. 20510-1904

SUSAN M. COLLINS  
MAINE

112 RUSSELL SENATE OFFICE BUILDING  
WASHINGTON, DC 20510  
202/224-2523  
202/224-2693 FAX

COMMITTEES  
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ON AGING

# United States Senate

WASHINGTON, DC 20510-1904

June 11, 1999

Ms. Diane Thompson  
Associate Commissioner for Legislative Affairs  
U.S. Dept of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, 1555 Parklawn Building  
Rockville, MD 20857


Dear Ms. Thompson:

Enclosed is a copy of correspondence I received from Ms. Barbara Werdelin of South Berwick, Maine. Ms. Werdelin is concerned about the proposed rule that would alter labeling requirements on food that has been treated with ionizing radiation. I would appreciate it if you would review her comments and respond directly to her concerns at the following address:

Ms. Barbara Werdelin  
33 Farmgate Road  
South Berwick, Maine 03908

Thank you for your attention to this matter.

Sincerely,

  
Susan M. Collins  
United States Senator

SMC:psi

Enclosure

No. 99-4296



AG 12 FOODS

33 Farmgate Road  
South Berwick, Maine 03908-1800  
May 17, 1999

The Honorable Senator Susan M. Collins  
B40 Dirksen Senate Office Building  
Washington, DC 20510

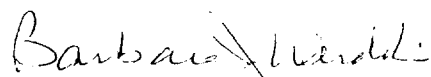
Dear Senator Collins:

I have recently been made aware of a frightening development at the Food and Drug Administration. Under pressure from food manufacturers and supporters of the nuclear industry, the FDA is considering a rule that would remove labeling requirements for foods treated with radiation. The public only has until May 18 to voice its objections to this rule. Currently, any food treated with radiation during the production process is labeled with a symbol known as a radura (the international symbol for irradiated foods) and either a statement saying "treated with radiation" or "treated by irradiation." The rule before the FDA would allow manufacturers to sell any and all irradiated foods to the consumer with nary a mention of the use of radiation during processing. This is bad for consumers.

Despite the fact that the FDA has determined that radiation is safe for food, many consumers, including myself, do not want to eat foods treated with radiation. Radiation changes the texture, taste, nutritional value, and chemical composition of foods. Radiation creates a heretofore unseen class of unique radiolytic products that have never been tested for their possible carcinogenic effects on humans. These are things that I do not want to put into my body.

This is a clear cut issue of a consumer being able to know what is in their food. We know what the fat, protein, carbohydrate, and vitamin content is in our food, why can we not know whether our food has been treated with radiation emanating from some of the most deadly substances known to man? I implore you, as a constituent and a friend, to write a letter to the FDA about this issue and ask them why your constituents should be kept in the dark about whether their food has been irradiated and why the comment period has been so short. Enclosed you will find the letter that I wrote to the FDA about this issue. I hope it is helpful in formulating your own comments.

Sincerely,

  
Barbara J. Werdelin

Enclosure

RECEIVED MAY 17 1999

33 Farmgate Road  
South Berwick, Maine 03908-1800  
May 17, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket No. 98N-1038, Irradiation in the Production, Processing, and  
Handling of Food

To whom it may concern:

I support the recommendation by the Center for Science in the Public Interest regarding labeling  
of irradiated foods:

"any foods, or any foods containing ingredients that have been treated by  
irradiation, should be labeled with a written statement on the principal display  
panel indicating such treatment. The statement should be easy to read and  
placed in close proximity to the name of the food and accompanied by the  
international symbol. If the food is unpackaged, this information should be  
clearly displayed on a poster in plain view and adjacent to where the product is  
displayed for sale."

Like other labels, irradiation labels are required by the FDA to be truthful and not misleading. I  
believe that the terms "treated with radiation" or "treated by irradiation" should be retained. Any  
phrase involving the word "pasteurization" is misleading because pasteurization is an entirely  
different process of rapid heating and cooling.

I recognize the radura as information regarding a material fact of food processing. The  
requirement for irradiation disclosure (both label and radura) should not expire at any time in the  
future. The material fact of processing remains. Even if some consumers become familiar with  
the radura, new consumers (e.g., young people, immigrants) will not be. The symbol should be  
clearly understandable at the point of purchase for everyone. If there is no label, consumers will  
be misled into believing the food has not been irradiated.

I urge you to extend the comment period past its current end date of May 18 to allow more  
concerned citizens the time to write in about this issue. Also, please place the comments  
received on the Internet so that the public can be informed about who is participating in this  
comment process.

Sincerely,

  
Barbara J. Werdelin

RECEIVED MAY 18 1999